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7	Attorneys for Plaintiff NUVASIVE, INC.				
8	UNITED STATES DISTRICT COURT				
9	SOUTHERN DISTRICT OF CALIFORNIA				
10		Case No. 12CV3065 BTM JMA			
11	NUVASIVE, INC.,				
12	Plaintiff,	COMPLAINT FOR PATENT INFRINGEMENT			
13	CADWELL INDUSTRIES, INC., DEMAND FOR JURY TRIAL				
14					
15	Defendant.				
16	DI ' .'CCN II .' I . ((NI II .' )				
17	Plaintiff NuVasive, Inc. ("NuVasive") files this Complaint and Demand for Jury Trial				
18	seeking relief for patent infringement by Defendant Cadwell Industries, Inc. ("Cadwell"), stating				
19	and alleging the following:				
20	I. PARTIES				
21	A. NuVasive, Inc.				
22	1. Plaintiff NuVasive, Inc. is a corporation organized and existing under the laws of				
23	the State of Delaware with its principal place of business in San Diego, California.				
24	2. NuVasive is an innovative medical device company focused on developing				
25	minimally disruptive surgical products and procedures for the spine. NuVasive makes and sells				
26	over 75 products spanning the entirety of the spine for reconstructive surgery and including				
27	neuromonitoring devices and services as well as a biologics portfolio. NuVasive's product				
28	development focus has been the innovation of products that treat spine disorders in a minimally				
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invasive fashion to deliver unmatched surgical outcomes with minimal collateral disruption to patients' health and wellbeing.

- 3. Founded in 1999, NuVasive has experienced extraordinary growth and currently is the fourth-largest spine company in the U.S., and the fifth-largest globally. NuVasive employs or engages more than 1,500 people at its corporate headquarters in San Diego, California and at its additional offices around the world.
- 4. NuVasive is well known for developing the XLIF® ("eXtreme Lateral Interbody Fusion") procedure, a minimally disruptive procedure that allows spine surgeons to have direct access to the intervertebral disc space (the "joint" of the spine) from the side of the body, as opposed to from the front or back. A traditional "open" spine surgery often requires an incision that is at least 4-6 inches and causes significant trauma when accessing a patient's spine from the front or back, whereas XLIF typically requires an incision that is much smaller and results in significantly less patient trauma. NuVasive's XLIF procedure has helped many patients experience extraordinary results—they are often walking the same day of surgery, experiencing less blood loss and trauma, spending less time in the hospital, and are back to work within weeks (versus months following traditional back surgery).
- 5. NuVasive also has developed a revolutionary intraoperative neuromonitoring system (NVJJB®/M5®, hereinafter "NVM5"), designed to help promote nerve and spinal cord safety and reduce the incidence of injury to neural elements during spinal procedures by providing real-time feedback and notifying surgeons immediately of any neurological insult. This intraoperative neuromonitoring allows a surgeon to avoid contact with nerves during the course of the surgical procedure. For example, during the XLIF procedure the surgeon inserts elongated dilators through a small incision in the patient's side and through the muscle on the side of the vertebrae (psoas muscle) to reach the spine. During this process the surgeon does not have a clear view of the psoas and cannot easily identify and avoid nerves. The NVM5 system solves this problem by continually scanning for nerves and providing instant audio and/or visual feedback when a nerve response is detected, helping the surgeon reach the appropriate spot on the spine for the repair while avoiding damage to nearby nerves.

- 6. Additionally, NuVasive's revolutionary nerve detection and monitoring system is used in connection with spinal procedures, including a majority of the XLIF procedures performed, that involve implantation of pedicle screws into the spine to secure intervertebral implants. In the context of pedicle screw implantation and testing, NuVasive's NVM5 system allows a surgeon to test the integrity of the bone surrounding the pedicle screw by monitoring the activity of the nerve adjacent the pedicle. If a neuromuscular response is evoked with a low enough level of stimulation, it may indicate that the bone has cracked during preparation for or implantation of the pedicle screw and exposed the nerve to potential hazard. The NVM5 system uses color-coded ranges and audible tones to immediately notify the surgeon of the suitability of screw placement and relative safety of the nerve. NVM5 is used before, during and after pedicle screw implantation to prevent contact with nerves and facilitate optimal placement of the screws.
- 7. NuVasive's products and procedures, including its XLIF procedure and NVM5 neuromonitoring system, have been used in hundreds of thousands of spine surgeries.
- 8. NuVasive has been granted dozens of patents in the area of lateral access spinal surgery and intraoperative neuromonitoring, including the five patents asserted in this action.

# B. Cadwell Industries, Inc.

- 9. Defendant Cadwell is a corporation organized and existing under the laws of the State of Washington with a principal place of business in Kennewick, Washington.
- 10. Cadwell manufactures and sells a variety of medical devices in the area of neurophysiology, including the Cascade<sup>®</sup> line of intraoperative neuromonitoring systems. This line of products includes at least the Cascade, Cascade Pro and Cascade Elite systems.
- 11. On information and belief, Cadwell has sold the Cascade products since at least 2006, marketing them as neuromonitoring systems designed for use in a variety of surgical procedures.
- 12. Cadwell sells its Cascade system with NerveGuard<sup>®</sup>, an "automated pedicle screw testing feature." NerveGuard "finds and reports stimulus threshold" during screw testing, which the surgeon can use to determine whether the pedicle screw is properly seated, and whether there

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are any cracks in the bone. Like NuVasive's patented NVM5 system, NerveGuard uses a "[1]arge color-coded reporting window and tones to let the surgeon instantly know the screw threshold."

- 13. In late 2011, Cadwell began marketing and selling its Cascade systems for use in lateral spinal access surgery, advertising a "lateral module" for use in a procedure that infringes NuVasive's patents. According to Cadwell's marketing materials for its Cascade system, the "Cascade and software includes a lateral access module which allows monitoring of lateral access cases[.]" Cadwell further advertises that the lateral access module employs an "[i]ntelligent, nerve-hunting algorithm" that "provides audio and visual feedback in real-time on nerve proximity via threshold detection." Like NuVasive's NVM5 system, Cascade's lateral module provides visual feedback in the form of green, yellow and red threshold ranges to indicate relative distance and proximity to a nerve.
- 14. NuVasive notified Cadwell of its infringement in or about October 2012, specifically identifying the asserted patents that Cadwell's products infringe. Despite being notified of its infringing conduct, Cadwell has continued to infringe the asserted patents by marketing, selling, and providing training on the operation of its Cascade system.

#### JURISDICTION AND VENUE II.

- 15. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and 1338.
- 16. This Court has personal jurisdiction over Defendant Cadwell pursuant to California Code of Civil Procedure § 410.10. On information and belief, Cadwell has knowingly and purposefully directed its wrongful acts to this forum, distributed, advertised and/or sold products embodying NuVasive's inventions in this forum, actively solicited business in this forum, and utilized interactive websites that permit residents of this forum to purchase products embodying NuVasive's inventions over the internet and have these products shipped into this forum.
- 17. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400 as Plaintiff NuVasive is headquartered in this district, and Defendant Cadwell is subject to personal jurisdiction in this judicial district, has done business in this judicial district, has committed acts

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of patent infringement in this judicial district, and continues to commit such acts in this judicial district.

#### FIRST CLAIM FOR RELIEF

### (Infringement of U.S. Patent No. 7,522,953)

- 18. Plaintiffs repeat and incorporate by reference the allegations set forth above.
- 19. On April 21, 2009, United States Patent Number 7,522,953 (the "'953 Patent") entitled "System and Methods for Performing Surgical Procedures and Assessments" was duly issued to NuVasive, Inc. A true and correct copy of the '953 Patent is attached hereto as Exhibit 1.
  - 20. The '953 Patent is valid and enforceable.
- 21. NuVasive is the owner, by assignment from the inventors, of all right, title and interest in and to the '953 Patent
- 22. Defendant Cadwell advertises, offers for sale, sells and/or facilitates the sale of products that infringe the '953 Patent, either literally and/or through the doctrine of equivalents. The product lines sold by Cadwell that infringe the '953 Patent include, but are not necessarily limited to Cascade, Cascade Elite and Cascade Pro.
- 23. Cadwell had actual or constructive knowledge of NuVasive's patent rights, knew or should have known that the advertisement, offer for sale, sale, and facilitating of sale of the infringing products would induce actual infringement, and/or acted with willful blindness to NuVasive's patent rights because, *inter alia*, in or about October 2012 and thereafter, NuVasive directly informed Cadwell of its patent rights and that Cadwell was advertising, offering for sale, selling, and facilitating the sale of the infringing products.
- 24. Cadwell has infringed and continues to infringe NuVasive's '953 Patent by direct infringement, contributory infringement, and/or inducing others to infringe in violation of 35 U.S.C. § 271, through the advertising, using, selling, offering for sale, facilitating of sale, and/or importation of at least the infringing Cascade, Cascade Elite, and Cascade Pro lines of products,

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and by promoting, teaching and/or providing training on the infringing use of at least the Cascade, Cascade Elite, and Cascade Pro lines of products.

- 25. On information and belief, Cadwell's infringement of one or more claims of the '953 Patent has been and continues to be willful, wanton and deliberate.
- 26. NuVasive is damaged and irreparably injured by Cadwell's infringing activities and will continue to be so damaged and irreparably injured unless and until Cadwell's infringing activities are enjoined by this Court.

# SECOND CLAIM FOR RELIEF

# (Infringement of U.S. Patent 8,068,912)

- 27. Plaintiffs repeat and incorporate by reference the allegations set forth above.
- 28. On November 29, 2011, United States Patent Number 8,068,912 (the "'912 Patent") entitled "System and Methods for Determining Nerve Proximity, Direction, and Pathology During Surgery" was duly issued to NuVasive, Inc. A true and correct copy of the '912 Patent is attached hereto as Exhibit 2.
  - 29. The '912 Patent is valid and enforceable.
- 30. NuVasive is the owner, by assignment from the inventors, of all right, title and interest in and to the '912 Patent.
- 31. Defendant Cadwell advertises, offers for sale, sells and/or facilitates the sale of products that infringe the '912 Patent. The product lines sold by Cadwell that infringe the '912 Patent include, but are not necessarily limited to Cascade, Cascade Elite and Cascade Pro.
- 32. Cadwell had actual or constructive knowledge of NuVasive's patent rights, knew or should have known that the advertisement, offer for sale, sale, and facilitating of sale of the infringing products would induce actual infringement, and/or acted with willful blindness to NuVasive's patent rights because, *inter alia*, in or about October 2012 and thereafter, NuVasive directly informed Cadwell of its patent rights and that Cadwell was advertising, offering for sale, selling, and facilitating the sale of the infringing products.

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- 33. Cadwell has infringed and continues to infringe NuVasive's '912 Patent by direct infringement, contributory infringement, and/or inducing others to infringe in violation of 35 U.S.C. § 271, through the advertising, using, selling, offering for sale, facilitating of sale, and/or importation of at least the infringing Cascade, Cascade Elite, and Cascade Pro lines of products, and by promoting, teaching and/or providing training on the infringing use of at least the Cascade, Cascade Elite, and Cascade Pro lines of products.
- 34. On information and belief, Cadwell's infringement of one or more claims of the '912 Patent has been and continues to be willful, wanton and deliberate.
- 35. NuVasive is damaged and irreparably injured by Cadwell's infringing activities and will continue to be so damaged and irreparably injured unless and until Cadwell's infringing activities are enjoined by this Court.

# THIRD CLAIM FOR RELIEF

# (Infringement of U.S. Patent 8,027,716)

- 36. Plaintiffs repeat and incorporate by reference the allegations set forth above.
- 37. On September 27, 2011, United States Patent Number 8,027,716 (the "'716 Patent") entitled "System and Methods for Performing Surgical Procedures and Assessments" was duly issued to NuVasive, Inc. A true and correct copy of the '716 Patent is attached hereto as Exhibit 3.
  - 38. The '716 Patent is valid and enforceable.
- 39. NuVasive is the owner, by assignment from the inventors, of all right, title and interest in and to the '716 Patent.
- 40. Defendant Cadwell advertises, offers for sale, sells and/or facilitates the sale of products that infringe the '716 Patent. The product lines sold by Cadwell that infringe the '716 Patent include, but are not necessarily limited to Cascade, Cascade Elite and Cascade Pro.
- 41. Cadwell had actual or constructive knowledge of NuVasive's patent rights, knew or should have known that the advertisement, offer for sale, sale, and facilitating of sale of the

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infringing products would induce actual infringement, and/or acted with willful blindness to NuVasive's patent rights.

- 42. Cadwell has infringed and continues to infringe NuVasive's '716 Patent by direct infringement, contributory infringement, and/or inducing others to infringe in violation of 35 U.S.C. § 271, through the advertising, using, selling, offering for sale, facilitating of sale, and/or importation of at least the infringing Cascade, Cascade Elite, and Cascade Pro lines of products, and by promoting, teaching and/or providing training on the infringing use of at least the Cascade, Cascade Elite, and Cascade Pro lines of products.
- 43. On information and belief, Cadwell's infringement of one or more claims of the '716 Patent has been and continues to be willful, wanton and deliberate.
- 44. NuVasive is damaged and irreparably injured by Cadwell's infringing activities and will continue to be so damaged and irreparably injured unless and until Cadwell's infringing activities are enjoined by this Court.

# FOURTH CLAIM FOR RELIEF

# (Infringement of U.S. Patent 7,935,051)

- 45. Plaintiffs repeat and incorporate by reference the allegations set forth above.
- 46. On May 3, 2011, United States Patent Number 7,935,051 (the "'051 Patent") entitled "Surgical Access System and Related Methods" was duly issued to NuVasive, Inc. A true and correct copy of the '051 Patent is attached hereto as Exhibit 4.
  - 47. The '051 Patent is valid and enforceable.
- 48. NuVasive is the owner, by assignment from the inventors, of all right, title and interest in and to the '051 Patent.
- 49. Defendant Cadwell advertises, offers for sale, sells and/or facilitates the sale of products that infringe the '051 Patent. The product lines sold by Cadwell that infringe the '051 Patent include, but are not necessarily limited to Cascade, Cascade Elite and Cascade Pro.
- 50. Cadwell had actual or constructive knowledge of NuVasive's patent rights, knew or should have known that the advertisement, offer for sale, sale, and facilitating of sale of the

infringing products would induce actual infringement, and/or acted with willful blindness to NuVasive's patent rights.

- 51. Cadwell has infringed and continues to infringe NuVasive's '051 Patent by direct infringement, contributory infringement, and/or inducing others to infringe in violation of 35 U.S.C. § 271, through the advertising, using, selling, offering for sale, facilitating of sale, and/or importation of at least the infringing Cascade, Cascade Elite, and Cascade Pro lines of products, and by promoting, teaching and/or providing training on the infringing use of at least the Cascade, Cascade Elite, and Cascade Pro lines of products.
- 52. On information and belief, Cadwell's infringement of one or more claims of the '051 Patent has been and continues to be willful, wanton and deliberate.
- 53. NuVasive is damaged and irreparably injured by Cadwell's infringing activities and will continue to be so damaged and irreparably injured unless and until Cadwell's infringing activities are enjoined by this Court.

# FIFTH CLAIM FOR RELIEF

# (Infringement of U.S. Patent No. 8,050,769)

- 54. Plaintiffs repeat and incorporate by reference the allegations set forth above.
- 55. On November 1, 2011, United States Patent Number 8,050,769 (the "'769 Patent") entitled "System and Methods for Determining Nerve Proximity, Direction, and Pathology During Surgery" was duly issued to NuVasive, Inc. A true and correct copy of the '769 Patent is attached hereto as Exhibit 5.
  - 56. The '769 Patent is valid and enforceable.
- 57. NuVasive is the owner, by assignment from the inventors, of all right, title and interest in and to the '769 Patent
- 58. Defendant Cadwell advertises, offers for sale, sells and/or facilitates the sale of products that infringe the '769 Patent. The product lines sold by Cadwell that infringe the '769 Patent include, but are not necessarily limited to Cascade, Cascade Elite and Cascade Pro.

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- 59. Cadwell had actual or constructive knowledge of NuVasive's patent rights, knew or should have known that the advertisement, offer for sale, sale, and facilitating of sale of the infringing products would induce actual infringement, and/or acted with willful blindness to NuVasive's patent rights.
- 60. Cadwell has infringed and continues to infringe NuVasive's '769 Patent by direct infringement, contributory infringement, and/or inducing others to infringe in violation of 35 U.S.C. § 271, through the advertising, using, selling, offering for sale, facilitating of sale, and/or importation of at least the infringing Cascade, Cascade Elite, and Cascade Pro lines of products, and by promoting, teaching and/or providing training on the infringing use of at least the Cascade, Cascade Elite, and Cascade Pro lines of products.
- 61. On information and belief, Cadwell's infringement of one or more claims of the '769 Patent has been and continues to be willful, wanton and deliberate.
- 62. NuVasive is damaged and irreparably injured by Cadwell's infringing activities and will continue to be so damaged and irreparably injured unless and until Cadwell's infringing activities are enjoined by this Court.

#### PRAYER FOR RELIEF

WHEREFORE, Plaintiff NuVasive prays for judgment as follows:

- A. A judgment that Cadwell has infringed and continues to infringe U.S. Patents Nos. 7,522,953, 8,068,912, 8,027,716, 7,935,051 and 8,050,769 in violation of 35 U.S.C. § 271;
- C. Preliminary and permanent injunctive relief pursuant to 35 U.S.C. § 283 against any further infringement, active inducement of infringement, and contributory infringement of U.S. Patents Nos. 7,522,953, 8,068,912, 8,027,716, 7,935,051 and 8,050,769 by Cadwell, its officers, agents, servants, employees, attorneys, and those persons in active concert or participation with Cadwell;
- D. An award of damages pursuant to 35 U.S.C. § 284 arising out of Cadwell's infringement of U.S. Patents Nos. 7,522,953, 8,068,912, 8,027,716, 7,935,051 and 8,050,769, together with prejudgment and post-judgment interest;
  - E. A determination that Caldwell's infringement is and was willful and that this is an

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1	exceptional case under 35 U.S.C. § 285;			
2	F.	An award of enhanced damages and the attorneys' fees and costs incurred by		
3	Plaintiff NuV	tiff NuVasive; and		
4	G.	For such other and	further relief as the Court may deem just and proper.	
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6	Dated: Dece	mber 27, 2012	MORRISON & FOERSTER LLP	
7				
8			By: /s/ Eric M. Acker Eric M. Acker	
9			Attorneys for Plaintiff	
10			NUVAŠIVE, INC.	
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